

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42 EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**



Manufacturer:

SHENZHEN ANTMED CO.,LTD

Add: 18 Jinhui Ave., Pingshan New District, Shenzhen,
518122, China

MEDICAL DEVICE:

Contrast Media Injectors

SPECIFICATION:

ImaStar CDP, ImaStar CSP, ImaStar CDC, ImaStar MDP,
ImaStar ASP

CLASSIFICATION:

CLASS IIb, RULE 10

CONFORMITY ASSESSMENT ROUTE: ANNEX II excluding (4)

We, the manufacturer, here with declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices;

Including, at 21 March 2010, the amendments by Council Directive 2007/47/EEC.

All supporting documentation is retained at the premises of the manufacturer.

(WE, AS MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.)

NOTIFIED BODY:

TÜV SÜD Product service GmbH
Ridlerstr 65, 80339 München, Germany

IDENTIFICATION NUMBER:

CE 0123

(EC)CERTIFICATE(S):

G1 004593 0002 Rev.01

VALID UNTIL:

2024-05-26

EC REP

European Representative:

Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany.

START of CE-MARKING:

None

PLACE, DATE OF DECLARATION:

SHENZHEN, 2020-03-03

SIGNATURE:

NAME: MR. FENG GAO

POSITION: MANAGEMENT REPRESENTATIVE